## NRG Cancer Care Delivery Research **Committee Meeting**

Mary E. Cooley, PhD, RN, FAAN, CCDR Chair Matthew Hudson, PhD, MPH, CCDR Vice-Chair

> **NRG Oncology Winter Meeting** February 11, 2022











## NRG NCORP Cancer Care Delivery Research Priorities

#### Concepts/protocols focused on:

- Integrating patient-reported outcomes into clinical practice (extends survival);
- Enhance access to proven survivorship and palliative care strategies optimizing survivor and family quality of life;
- Optimize screening strategies based on disease risk including patients in the post-treatment surveillance phase of care; and
- Implement evidence-based symptom management strategies addressing patients' needs during both active adjuvant and palliative treatment.





#### **CCDR Announcements**

## Monthly CCDR committee meetings starting March 2022

Opportunity to present your work and/or developing concept of interest

#### NCI webinars of interest

- Advancing rapid cycle research in cancer care, February 16-17, 2022
- Disparities among sexual and gender minority cancer survivors: Studies on prostate cancer among gay and bisexual men, February 15, 2022
- Webinar series: Telehealth and cancer: Studying its role in cancer control and care delivery, Monthly series from February 25, 2022-June 21, 2022



### Landscape survey

Thank you to NRG CCDR committee members for participating in the development and review of landscape survey!

> Melyssa Foust Andrew McDonald Nitin Ohri









## **Developing CCDR concepts**

Developing CCDR concepts and protocols						
A Randomized Phase II Study of Physical Activity Monitoring to Enhance the Delivery of Definitive Radiotherapy for Locally Advanced NSCLC (NRG Foundation trial)	N. Ohri, MD					
Exercise is Medicine in Medical Oncology	K. Schmitz, PhD; J. Trilk, PhD					
Implementation of Guideline-based Molecular Profiling of Early-Stage Endometrial Cancer through NCORP/NRG Oncology	A. Hagemann, MD					
Managing symptoms and psychological distress during oral anti-cancer tx	Alla Sikorski, PhD; Terry Badger, PhD					
Implementation of A Toolkit to Address Persistent Chronic Cancer Pain Syndromes (ATACC)	Jeannine Brant, PhD; Mary Cooley, PhD					
Sexual orientation and gender identity (SOGI) measurement for patient centered cancer care in sexual and gender minority (SGM) populations	Megan Mullins, PhD					



## **Open NRG NCORP Trials**

\*\*accrual as of February 1, 2022

Study No	Disease Site	Description	Date Activated	Target Accrual	Total Accrual	NCORP Accrual (%)	Expected Closure Date
NRG- CC007CD	Prostate	Survivorship care plan for prostate ca survivors on ADT to increase blood glucose and cholesterol checks in yr 2 after starting ADT & lower CVD risk	03/27/19	544	473	100%	April 2022



NRG-CC007CD NCORP Practices with Completed

AnMed Health Cancer Center

CoxHealth Radiation Oncology

Geisinger Medical Center

Kaiser Permanente Northern California

MaineHealth Radiation Therapy

Medical Group of the Carolinas-Radiation

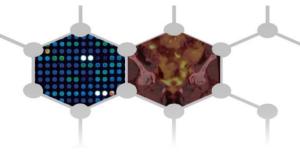
Oncology

NCORP of the Carolinas

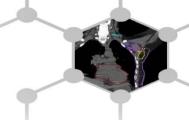
The University of Kansas Cancer Center











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## ATACCp: Effectiveness and Implementation of A Toolkit to Address Persistent Chronic Cancer Pain



Jeannine M. Brant, PhD, APRN, AOCN, FAAN Mary E. Cooley, PhD, RN, FAAN Patricia Ganz, MD













## **Disclosures**

None



#### Preliminary Data: NRG NCORP Member Symptom Management Survey

- Email solicitation to NCORP Contact Pls and Lead Research Associates (June 2021)
  - Initial e-mail contacts may have forwarded correspondence to individuals presumed better able to answer questions.
- Respondents accessed survey via link (survey monkey)
  - Survey sent to 87 respondents
  - Response from 72 respondents
  - 82.7% response rate



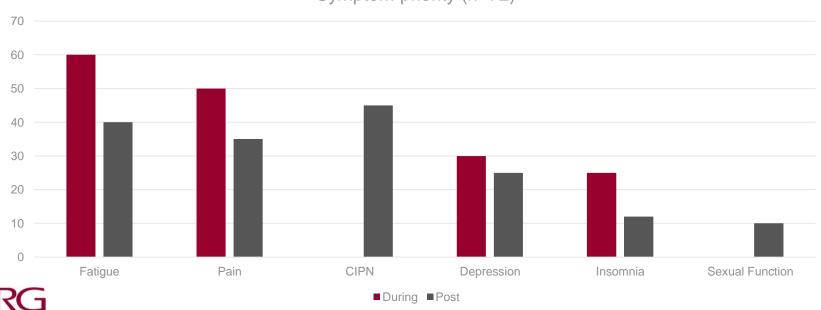
## **Survey Questions**

- Rank the top three symptoms for evidence-based symptom management <u>during</u> treatment (1st to 3rd)"
- Rank the top three symptoms for evidence-based symptom management <u>post</u> treatment (1<sup>st</sup> to 3<sup>rd</sup>)
- Note supportive care management options available at [respondent's] site
- Note the supportive care management option [respondent] uses

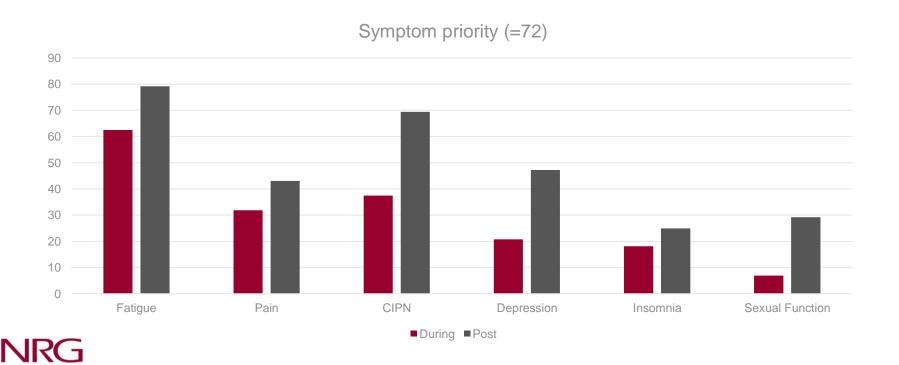


## Ranked as number 1 symptom priority (n=72)

Symptom priority (n=72)



## Ranked as a symptom priority (n=72)



#### Problem of Cancer Pain

#### **Chronic Cancer Pain**

- Cancer pain is a significant problem throughout the cancer trajectory
- Persistent in 39.3% of patients following cancer treatment
  - Prevalence rates in real world data of specific pain syndromes is lacking
- Most efforts have focused on pain in patients with active disease
- Few studies exist that focus on managing cancer-related pain posttreatment



## Types of Chronic Pain Syndromes

#### **Post-Surgical Pain**

- Post-mastectomy
- Post-thoracotomy
- Post-head/neck dissection

**Chemotherapy-Induced Peripheral Neuropathy** 

Myalgias from Aromatase Inhibitors
Post-Radiation Pain Syndromes

 Plexopathies – brachial and lumbosacral Variable presentation

Days

Weeks

Years





## Challenges

#### Long-term Follow-up

- Number of cancer survivors anticipated to grow exponentially
- Need to optimize functioning and quality of life in post-treatment survivors
- Early identification of chronic and persistent pain essential

#### **Lack of Consistent Assessment**

Lack of a tailored assessment to identify potential chronic pain syndromes

#### Lack of Knowledge

- Lack of knowledge and resources regarding approaches to management
- Fear of prescribing opioids in this potentially cured population



## Objective

 Evaluate the effectiveness of an implementation-strategy guided pain assessment and management toolkit among patients with chronic cancer pain syndromes in post-treatment cancer survivors with breast, colorectal, head and neck, lung, and prostate cancers treated in NCORP community-based practices



## Specific Aims

- Determine the effectiveness of the ATACCp toolkit as measured by the 1) percentage of eligible patients who are screened for pain and 2) percentage of eligible patients that are referred to supportive care services for pain management between the intervention vs. usual care groups using a randomized cluster design
- 2. Determine differences in pain severity levels and functional impairment between patients in the intervention vs. usual care groups using a randomized cluster design.
- 3. Examine the types of implementation strategies that are used by sites that are associated with increased uptake of the ATACCp toolkit



#### Patient Inclusion Criteria

- Adult patients age 18 and older
- Cognitively intact; able to report pain and assessment parameters
- Diagnosed with breast, colorectal, prostate, lung, or head/neck cancer within the past 2 years
- Completed cancer treatment with curative intent within the past year
- Screen positive for a pain syndrome that is presumed to be attributed to receipt of cancer therapy (e.g. surgery, chemotherapy, radiation therapy)
- Pain intensity of ≥4 during the past week



#### Site Inclusion Criteria

- Sites that treat and follow patients with breast, colorectal, prostate, lung, or head/neck cancer
- NCORP based practices
- Clinical champion on site to participate as part of study team
- May or may not have implemented patient-reported outcome measures



## ATACCp Toolkit

The pain assessment and management toolkit will include:

- A standardized pain assessment tool that can be integrated into the workflow processes
- A menu of multimodal pharmacologic and nonpharmacologic options, including supportive care/rehabilitation/physical therapy referrals, to manage pain with a focus on non-opioid strategies
- Help in identifying local resources for referrals



## Implementation Strategies



#### Chronic cancer pain syndromes

- Pain Assessment Tools
- Pharmacologic Management
- Nonpharmacologic Management



#### Menu of PROMIS measures

- Evidence-based pain management guidelines and checklists
- Pharmacologic strategies tailored to each pain syndrome
- Opioid downward titration guidelines
- Nonpharmacologic strategy options tailored to pain characteristics
- Quality improvement tools



## Site ser lead students with the ser lead student

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- Site Champions will serve as a liaison to lead and facilitatethe study at each site
- Virtual site visits
- Welcome meeting
- Monthly Community of Practice meetings to share best practices
- Audit & Feedback sessions





## Questions





#### NRG CCDR Research Fellowship Scholarship

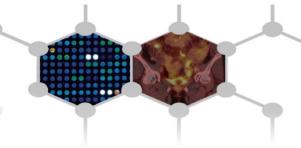




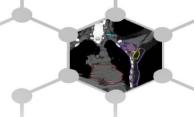
Megan Mullins, PhD

Sexual orientation and gender identity (SOGI) measurement for patient centered cancer care in sexual and gender minority (SGM) populations









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# Sexual orientation and gender identity (SOGI) measurement for patient centered cancer care in sexual and gender minority (SGM) populations

Megan A. Mullins, PhD, MPH NRG Oncology CCDR Meeting February 11, 2022









## **Disclosures**

• I have no disclosures to report.



## Study Team

Megan Mullins, PhD, MPH, University of Michigan Rogel Cancer Center

Marina Stasenko, MD, Gynecologic Oncology, NYU Grossman School of Medicine

#### **Co-Investigators**

Lauren Wallner, PhD, MPH, University of Michigan Rogel Cancer Center Mary Cooley, PhD, RN, FAAN, Dana Farber/ Harvard Cancer Center Matthew Hudson, PhD, MPH, Prisma Health



## Cancer Care for SGM Populations

- SGM were formally designated a health disparity population by National Institute of Health in 2016.
- Cancer disparities
  - Lower rates of cancer screening
  - Higher rates of certain cancers (anal, cervical, skin)
  - Later stages at diagnosis
  - Lower quality of cancer care
    - Patient-provider communication
    - Discrimination



A 2017 assessment found that only 1 in 5 NCORP practice groups routinely collect sexual orientation data, and only 1 in 10 routinely collect patient gender identity beyond male or female.



#### Sexual orientation measure

#### Do you think of yourself as:

- Lesbian, gay, or homosexual
- Straight or heterosexual
- Bisexual
- Something else(e.g. queer, pansexual, asexual)
- Don't know
- Choose not to disclose



## Gender identity measure

#### What is your current gender identity?

- Male
- Female
- Transgender man/transgender male
- Transgender woman/transgender female
- Other (e.g. non-binary, genderqueer, gender fluid, genderdiverse)
- Choose not to disclose

### What sex were you assigned at birth?

- Male
- Female



## Aims of this Study

**Aim 1:** To identify barriers and facilitators to SOGI measurement at the provider and system levels.

**Aim 2A:** To identify and prioritize implementation strategies to support SOGI measurement across NCORP sites.

**Aim 2B:** To refine intervention strategies and assess preliminary acceptability, feasibility, and appropriateness of identified strategies among a sample of targeted end users.



## We are currently recruiting

#### **10 Practice Sites**

- -1 physician/ APRN/ PA
- -1 clinical staff member

20-30 minute Zoom interviews

Participants will be compensated with a \$40 Amazon gift card for their time



## How to participate

We are currently scheduling interviews with interested providers and staff at participating practices.

Erica Field will email a one-page information sheet after this meeting.

Email: mamull@umich.edu



## Acknowledgements

#### **Grant/Sponsor Acknowledgements**

- T32-CA236621
- 5-UG1-CA-189867-08











#### References

- -National LGBT Health Education Center. Updates-2020-to-Ready-Set-Go-publication. Published June 2020. Accessed June 2, 2021.
- -Kent EE, Wheldon CW, Smith AW, Srinivasan S, Geiger AM. Care delivery, patient experiences, and health outcomes among sexual and gender minority patients with cancer and survivors: A scoping review. *Cancer*. 2019;125(24):4371-4379. doi:10.1002/cncr.32388
- -Institute of Medicine (U.S.), ed. *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding*. National Academies Press; 2011.
- -Quinn GP, Sanchez JA, Sutton SK, et al. Cancer and Lesbian, Gay, Bisexual, Transgender/Transsexual, and Queer/Questioning Populations (LGBTQ). CA Cancer J Clin. 2015;65(5):384-400. doi:10.3322/caac.21288
- -Boehmer U, Miao X, Ozonoff A. Cancer survivorship and sexual orientation. Cancer. 2011;117(16):3796-3804. doi:10.1002/cncr.25950
- -Agénor M, Krieger N, Austin SB, Haneuse S, Gottlieb BR. Sexual Orientation Disparities in Papanicolaou Test Use Among US Women: The Role of Sexual and Reproductive Health Services. *Am J Public Health*. 2014;104(2):e68-e73. doi:10.2105/AJPH.2013.301548
- -Machalek DA, Poynten M, Jin F, et al. Anal human papillomavirus infection and associated neoplastic lesions in men who have sex with men: a systematic review and meta-analysis. *Lancet Oncol.* 2012;13(5):487-500. doi:10.1016/S1470-2045(12)70080-3
- -Singer S, Tkachenko E, Hartman RI, Mostaghimi A. Association Between Sexual Orientation and Lifetime Prevalence of Skin Cancer in the United States. *JAMA Dermatol.* 2020;156(4):441-445. doi:10.1001/jamadermatol.2019.4196





Nitin Ohri, MD

NRG CCDR pilot project results: *Physical Activity Monitoring to Predict Hospitalization in Advanced Cancer Patients* 



Nitin Ohri, MD, MS

Albert Einstein College of Medicine

Montefiore Medical Center

Department of Radiation Oncology

Why Study Wearables in Oncology?

Before Treatment Oncology? Enhanced monitoring for Improved evaluation of late toxicity or disease patients during treatment progression Better selection of patients fit for treatment Enhanced supportive care Promoting healthful for patients with low lifestyles in the activity levels survivorship period **Improved Clinical** Outcomes Reduced Health **Care Expenditures Improved Cancer Improved Cancer Care Quality Care Value** 

## **Activity Monitoring During Cancer Treatment at Montefiore/Einstein**

Trial	Disease Sites	Treatment	N	EORTC QLQ- C30	PRO- CTCAE	Wearable Device	Status	
Activity Monitoring Pilot	Head/Neck, Lung, Gl	Concurrent chemoradiotherapy	38	Х		Х	Completed, Published	
Real-time Activity Monitoring to Prevent Admissions during RadioTherapy (RAMPART)	Head/Neck, Lung, Upper GI	Concurrent chemoradiotherapy	38	Х		Х	Completed, Presented	
A Simple Walking Program to Enhance Chemoradiotherapy Delivery	CNS, Head/Neck, Lung, GI, Cervix	Concurrent chemoradiotherapy	166	Х		Х	Accrual completed	
Activity Monitoring for Patients with Advanced Solid Tumors	Head/Neck, Lung, Gl	Intravenous systemic therapy	60	Х		Х	Accrual completed	
Selective Personalized RadioImmunotherapy for NSCLC Trial (SPRINT)	NSCLC	Concurrent chemoradiotherapy versus pembrolizumab and radiotherapy	63		Х	X	Accrual completed	
FLT3 Ligand, CD40 Agonist Antibody, and Stereotactic Radiotherapy versus Standard Therapy for Advanced Non-small Cell Lung Cancer: A Phase I/II Randomized Trial	NSCLC	Stereotactic radiotherapy and immunotherapy versus standard chemotherapy	46		Х	Х	Open to accrual	
PGHD Collection During Proton Chemoradiotherapy for Lung Cancer: A Pilot Study	Lung	Proton radiotherapy and concurrent chemotherapy	40		Х	Х	Upcoming	
NRGF-001: Activity Monitoring to Improve Patient Care during Chemoradiotherapy for LA-NSCLC	NSCLC	Concurrent chemoradiotherapy	144	Х	Х	Х	Upcoming	
Selective Personalized RadioImmunotherapy for NSCLC Trial (SPRINT) 2	NSCLC	Pembrolizumab and radiotherapy +/- chemotherapy	36		Х	Х	Upcoming	



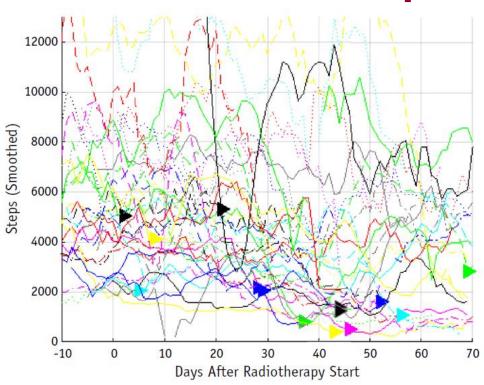




## Lessons so far

- Feasibility
  - Nearly all patients will agree wear a device
    - Most will keep it on
  - Few of our patients are willing to engage with a device
- Daily step counts are helpful
  - Easy to collect
  - Easy to interpret
  - Clinically relevant
    - Prognostic factor before treatment?
    - New vital sign during treatment?

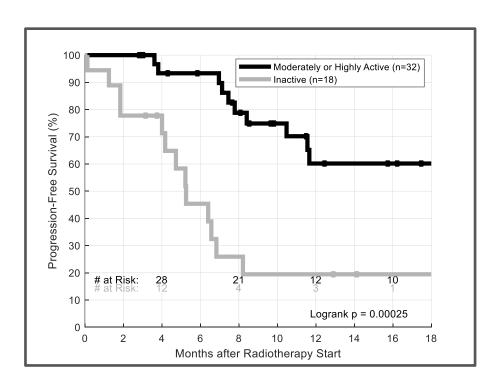
# Step Counts During Chemoradiotherapy and Hospitalization Risk



- Activity Monitoring Pilot Study
  - 14/38 subjects were hospitalized due to acute toxicities (triangles).
  - 38% reduction in the risk of hospitalization for every 1,000 steps taken each day (HR=0.62, p<0.001)</li>

# Prognostic Value of Baseline Activity Level in LA-NSCLC

- "Inactive" patients:
  - - 50% v. 9%, p=0.004
  - — ↓ rate of completing RT without delay >1 week
    - 67% v. 97%, p=0.006
  - − ↓ PFS
    - median 5.3 months v. 18.3 months, HR=4.52, p<0.001</li>
  - ↓ OS
    - median 15.0 months v. not reached, HR=3.88, p=0.007



### 3.1 Inclusion Criteria

- Age ≥ 18
- ECOG performance status 0-2
- Able to ambulate independently or with a cane (without the use of a walker)
- Planned or ongoing treatment with intravenous chemotherapy, intravenous immunotherapy, and/or intravenous targeted biologic therapy under the care of one of the study investigators and for one of the following diagnoses:
  - Metastatic head and neck cancer
  - Metastatic lung cancer (small cell or non-small cell), receiving 2<sup>nd</sup>-line (or beyond) therapy for advanced disease
  - Metastatic gastric, esophageal, pancreatic, or hepatobiliary cancer
  - Metastatic colorectal cancer, receiving 2<sup>nd</sup>-line (or beyond) therapy for advanced disease
- All patients must sign study specific informed consent prior to study entry.

### 4.2 Study Calendar

	Baseline	At each visit in Medical Oncology or Radiation Oncology for six months	At visits in Medical Oncology or Radiation Oncology beyond six months
History & Physical Examination	X	×	X
Toxicity Assessment	X	X	X
EORTC QLQ-C30	X	X*	(X*)
Activity Data Review		X	(X)

<sup>\* -</sup> will not be completed more than once in a week.

(X) – optional.





### 1.1 Primary Objective

 To demonstrate the feasibility of monitoring physical activity for patients with metastatic cancer who are receiving intravenous systemic therapy and providing that data to oncologists at each clinic visit.

"feasibility" = collecting data at ≥80% of clinic visits

### 1.2 Exploratory Secondary Objectives

- To assess associations between daily step counts and adverse clinical events, including emergency room visits, hospitalizations, decline in quality of life, and death.
- To assess associations between daily step counts and markers of aggressive end of life care, including administration of chemotherapy within the last 14 days of life, initiation of advanced radiotherapy treatments within the last 30 days of life, and hospice enrollment at least 3 days before death.

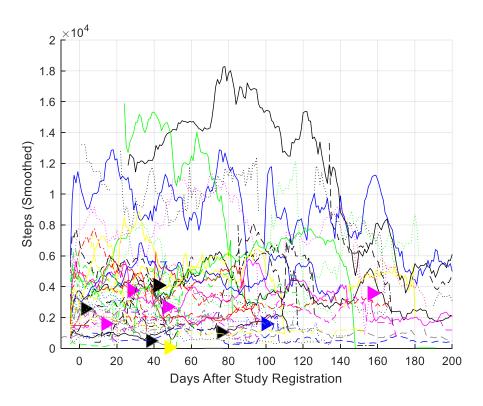
sample size: 60 subjects

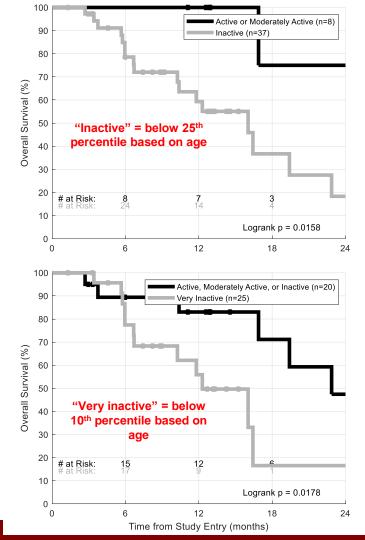
# **Update**

- 3/1/2018 IRB Approval
- 12/13/2018 Received funding from NRG CCDR Pilot Project Award
- 60 subjects enrolled between 3/28/2018 and 10/22/2021, 2 withdrew consent
  - 26 deaths
  - 38 subjects with hospitalizations
  - 38 subjects with ER visits
  - ≈400 med/rad onc visits within 6 months
    - Step data reviewed at ≈ 70% of visits
  - >6,000 days of step data collected

Age, median (range)	65 (42 to 79)
Gender	
Male	41
Female	19
Diagnosis	
Head and Neck Cancer	1
Lung Cancer	21
Esophageal Cancer	3
Gastric Cancer	4
Pancreatic Cancer	6
Primary Liver Cancer	15
Colorectal Cancer	8
Systemic Therapy at	
Registration	
IV Chemotherapy	33
IV Targeted therapy	8
IV Immunotherapy	27
ECOG Performance Status	
0	8
1	37
2	13
<del>-</del>	10

## **Interim Results**





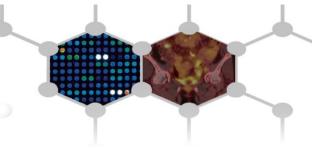
# **Questions?**



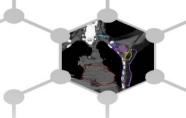
### Andrea Hagemann, MD

Implementation of guideline-based molecular profiling of early-stage endometrial cancer







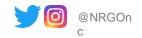


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## Implementation of Molecular Profiling in Endometrial Cancer: An NRG Landscape Mixed Methods Study

Andrea R. Hagemann, MD, MSCI Washington University in St. Louis School of Medicine

> NRG Semi-Annual Meeting, CCDR Committee Friday, February 11, 2022









## **Disclosures**

• I have no financial disclosures

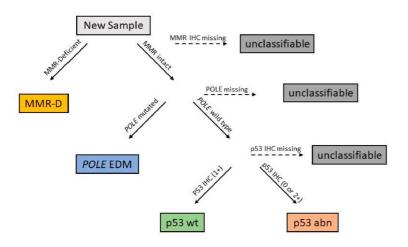


# Mapping the Landscape of Molecular Profiling in Endometrial Cancer

- How close are we to uniform guideline-based care across the US?
- What are the barriers and facilitators to guideline-based molecular profiling for EC?
- Would implementing uniform guideline-based care result in treatment changes?



## ProMisE Algorithm based on TCGA



**Figure 1.** The Proactive Molecular Risk Classifier for Endometrial Cancer (ProMisE) Algorithm to assess a new endometrial cancer sample. First, mismatch-repair (MMR)-deficiency is evaluated with immunohistochemistry (IHC) against MSH 6 and PMS2 proteins. Second, the Polymerase Epsilon (*POLE*) exonuclease domain is tested by sequencing exons 9–14. Lastly, IHC for p53 is performed to determine patients with normal expression (IHC score 1+) versus complete loss/null (IHC score 0) or accumulation (IHC score 2+). Reproduced with permission from [31].



### These Classifiers May Change Upfront Management

Table 1. 2020 ESGO/ESTRO/ESP prognostic risk group to guide adjuvant therapy use [11].

	Risk Group	Molecular Classification Unknown	Molecular Classification Known
Observe	Low	Stage IA endometrioid, grade 1–2, LVSI negative or focal	<ul> <li>Stage I–II POLE EDM endometrial carcinoma, no residual disease</li> <li>Stage IA MMRd/p53 wt endometrioid carcinoma + low grade + LVSI negative or focal</li> </ul>
Obs v.Vaginal brachy v. IO clinical trial	Intermediate	<ul> <li>Stage IB endometrioid, grade 1–2, LVSI negative or focal</li> <li>Stage IA endometrioid, grade 3, LVSI negative or focal</li> <li>Stage IA non-endometrioid (serous, clear cell, undifferentiated carcinoma, carcinosarcoma, mixed) without myometrial invasion</li> </ul>	<ul> <li>Stage IB MMRd/p53 wt endometrioid carcinoma + low-grade + LVSI negative or focal</li> <li>Stage IA MMRd/p53 wt endometrioid carcinoma + high-grade + LVSI negative or focal</li> <li>Stage IA p53 abn and/or non-endometrioid without myometrial invasion</li> </ul>
Obs v.Vaginal brachy v. Pelvic RT v.	High-intermediate	<ul> <li>Stage I endometrioid, substantial LSVI, regardless of grade and depth of invasion</li> <li>Stage IB endometrioid, grade 3, regardless of LVSI status</li> <li>Stage II</li> </ul>	<ul> <li>Stage I MMRd/p53 wt endometrioid carcinoma substantial LVSI regardless of grade and depth of invasion</li> <li>Stage IB MMRd/p53 wt endometrioid carcinoma high-grade regardless of LVSI status</li> <li>Stage II MMRd/p53 wt endometrioid carcinoma</li> </ul>
IO clinical trial  Pelvic RT v.	- High	<ul> <li>Stage III–IVA with no residual disease</li> <li>Stage I–IVA non-endometrioid (serous, clear cell, undifferentiated carcinoma, carcinosarcoma, mixed) with myometrial</li> </ul>	<ul> <li>Stage III–IVA MMRd/p53 wt endometrioid carcinoma with no residual disease</li> <li>Stage I–IVA p53abn endometrial carcinoma with myometrial invasion, with no residual disease</li> <li>Stage I–IVA p53 wt/MMRd serous,</li> </ul>
Chemo/RT v.		invasion, and with no residual disease	undifferentiated carcinoma, carcinosarcoma with myometrial invasion, with no residual disease
Chemo v. IO trials	Advanced	Stage III–IVA with residual disease     Chemo V.	Stage III–IVA with residual disease of any molecular type
	Metastatic	Stage IVB clinical trial	<ul> <li>Stage IVB of any molecular type</li> </ul>

European Society of Gynaecological Oncology (ESGO), European Society for Radiotherapy and Oncology (ESTRO), European Society of Pathology (ESP), lymphovascular space invasion (LVSI).

# 2022 NCCN Guidelines for Molecular Analysis of EC



# Comprehensive Cancer Endometrial Carcinoma

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#### PRINCIPLES OF MOLECULAR ANALYSIS

- Molecular analysis of endometrial carcinoma has identified four clinically significant molecular subgroups with differing clinical prognoses: *POLE* mutations, microsatellite instability-high (MSI-H), copy number low, and copy number high.<sup>13</sup>
- · Consider comprehensive genomic profiling via a validated and/or FDA-approved assay in the initial evaluation of uterine neoplasms.
- Ancillary studies for POLE mutations, mismatch repair (MMR)/MSI, and aberrant p53 expression are encouraged to complement morphologic assessment of histologic tumor type. <sup>14</sup> See Figure 1: Pathology and Genomics in Endometrial Carcinoma (ENDO-A 3 of 4).
- Universal testing of endometrial carcinomas for MMR proteins is recommended (MSI testing if results equivocal).
- > Testing may be performed on the initial biopsy or D&C material or the final hysterectomy specimen.
- MLH1 loss should be further evaluated for promoter methylation to assess an epigenetic mechanism.
- Genetic counseling, molecular analysis, and testing for all other MMR abnormalities is recommended.
- For those who are MMR-intact/MSI-stable or those who have not been screened, but who have a strong family history of endometrial and/or colorectal cancer, genetic counseling and testing is recommended. (See Lynch Syndrome/HNPCC in the NCCN Guidelines for Genetic/Familial High-Risk Assessment: Colorectal).
- Consider NTRK gene fusion testing for metastatic or recurrent endometrial carcinoma.
- Consider tumor mutational burden (TMB) testing through a validated and/or FDA-approved assay.



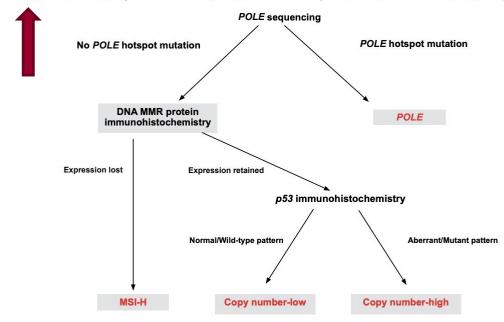
### NCCN Guidelines Version 1.2022 Endometrial Carcinoma

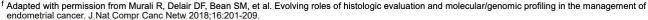
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#### PRINCIPLES OF MOLECULAR ANALYSIS

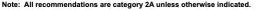
#### FIGURE 1: PATHOLOGY AND GENOMICS IN ENDOMETRIAL CARCINOMA

(The decision to use molecular testing/classification depends on the availability of resources and the multidisciplinary team of each center)<sup>f,g</sup>





<sup>&</sup>lt;sup>9</sup>Diagnostic algorithm for integrated genomic-pathologic classification of endometrial carcinomas.



Clinical Trials: NCCN believes that the best management of any patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged.





# Mixed Methods Survey/Interview Invite Coming Soon—Please Participate!

	PRISM Domain	Contextual Factors	holders, mapped to the PRISM Domain.  Implementation Assessment Measures		
			implementation Assessment Measures		
	Organizational Characteristics	-# Pathologists, Rad Oncs, Gyn Oncs per site -Pathologists' reporting structure -Site-specific gyn onc and radiation oncology practices for early-stage EC (vaginal brachytherapy, pelvic RT or none)	-Site stakeholder assessments by qualitative and quantitative interviews to define current patterns of practice -Time from Surgery to Pathology Report Signout -Sample pathology report review of EC staging (5 per site) - stage/histology/grade/demographics MMR status (reported? yes/no and result) p53 status POLE status		
	Patient Characteristics	Site's endometrial cancer patient demographics			
Su	NEY	Sta pleasing integrated reporting	The keh		
	plem	-Sites' leadership support of	Re tine Promise and the second		
	Imp m and Sustainability Framework	s cific : 1 f	e hat prohibit send out tess? Which reacts high these decisions? -Which larger academic sites offer NGS POLE testing, and which are ready to receive outside requests?		
	External Environment	-Readiness/availability of POLE send-out testing site -Site contracting negotiations	-Comparison of POLE testing at US academic sites to NCORP sites		
			-Site-specific surveys, matched to and compared with Lead Academic sites		



	We would now till a to understand how you perceive t	the benefits of	and harriors to	molooulou		
	We would next like to understand how you perceive the benefits of and barriers to molecular					
	testing in early-stage endometrial cancer.  MMR/MSI, p53, and POLE together are part of an endometrial classification algorithm known as ProMisE, and are recommended as part of the NCCN guidelines. Are you familiar with this NCCN algorithm?	I have never heard of this	I am aware of this			
SAMP	How confident are you that you would be able to	Not at all	(Place a mark  Moderately	on the scale above)		
	successfully implement molecular testing	confident	confident	Very confident		
			(Place a mark	on the scale above)		
	Obtaining MMR/MSI testing is currently recommended for all EC patients. For which patient populations do you think it is worthwhile or valuable to additionally obtain p53 and POLE status? (Select allthat apply)	High risk EC High-intermediate risk EC Low-intermediate risk EC Low risk EC None of the above				
	f"No set the above," is there any situation where you would much that tworthwhile or valuable to obtain this status?					
	How much would having pathogenic POLE testing change your practice patterns?	Not at all	A small amount	Quite a bit		
				on the scale above)		
	Having molecular testing information would help me counsel my patients.	Strongly disagree	Neither agree nor disagree	Strongly agree		
				on the scale above)		
	This information helps me involve my patient's preferences in decision making.	Strongly disagree	Neither agree nor disagree	Strongly agree		
				on the scale above)		

Molecular testing information would help me provide the appropriate treatment for my patients.



Strongly agree

Neither agree nor disagree

.....

## We Welcome Your Participation!

- Participant Recruitment by E-mail
  - Gyn Oncs
  - Rad Oncs
  - Pathologists
- Opportunity to invite other colleagues
- Invitation for a structured interview
- Gift card incentives for your time



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# Questions

hark you!

